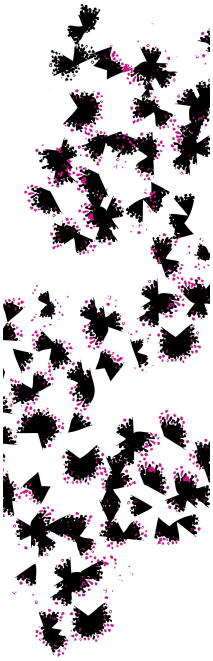

A Conceptual Design of a Needle Insertion Device for Compensation of Lesion Motion

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BSc Report

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Summary

Robot-assisted needle insertion has attracted considerable attention in recent years because of its promising application in minimally invasive percutaneous procedures such as tissue sample removal, localized drug delivery and brachytherapy. The success of these procedures depends on the accuracy and precision with which the target site is reached. Breathing-induced motion, tissue deformation and needle deflection, are among the main factors affecting accuracy of needle placement and needle-tip motion path. Complications associated with inaccurate placement have been studied and can include tissue damage, misdiagnosis, poor dosimetry and tumour seeding. The use of robot-assisted needle insertions have the potential to increase the success rate of these procedures by reaching targets deep inside the body while responding to respiration movement and avoiding sensitive structures.

This report describes a conceptual design of a needle insertion device that is able to adjust the needle path in order to reach a moving target by combining two motion management techniques; gating and chasing. The main focus of this work will be on compensating for breathing-induced motion of a lesion located in the liver.

Contents

1 Introduction

Minimally invasive procedures (MIP) are an important part of modern medicine. They result in less trauma, less complications and a shorter stay in hospital. An example of a wildly used form of MIP are percutaneous procedures. In surgery, a percutaneous procedure is any medical procedure or method where access to inner organs or other tissue is done via needle-puncture of the skin, rather than by using an "open" approach where inner organs or tissue are exposed. When the target is reachable via a straight trajectory, rigid needles are typically used. The surgeon carefully chooses the puncturing angle and pushes the needle forward in order to reach the target. Once the needle is inside the tissue, only small adjustments of the trajectory are possible. Complications associated with inaccurate placement have been studied and can include tissue damage, misdiagnosis and poor dosimetry.[1] Misestimating the puncturing angle also requires withdrawing and reinserting the needle, which elongates procedure times and increases patient discomfort. Human errors, imaging limitations, target uncertainty, tissue deformation and needle deflection are among the main factors affecting accuracy of needle placement and needle-tip motion path.[2; 3]

Human errors may be related to limitations with target visibility, target access and tool manoeuvrability. Target uncertainty may be caused by sudden patient movement or organ motion due to physiological processes (e.g. breathing). Needle deflection is generally due to the bevel tip and diameter of the needle. The tissue, into which the needle is inserted, may also contribute to needle deflection. The factors that affect tissue deformation include mechanical properties of soft tissue, needle tip contact force, and frictional forces between the tissue and the needle shaft.[3; 4]

To date, a number of researchers have explored ways to improve the process of needle insertion in trunk organs using robotics and medical imaging in order to improve the accuracy of the procedure. While human errors, imaging limitations, tissue deformation and needle deflection have been covert in numerous papers, solutions for movement caused by respiratory motion are almost non existing.

According to Shi et al[5], unexpected organ motion occurring because of respiration, during needle insertion can lead to serious problems. In such cases, misalignment between the presurgically planned position and the actual position of lesions could result in a target miss or inaccurate insertion of the needle, possibly leading to haemorrhage. One way to overcome this misalignment problem-not only in robotics surgery, but in clinical practice in general-is to have the patient hold his/her breath. Under such conditions, the surgeon has a limited time to locate the target lesion on the display and perform the operation. This can be a daunting task, particularly for an inexperienced surgeon. With the advent of robotic assisted surgery, two new motion management techniques emerged; gating and chasing. Gating is a technique that restricts the medical intervention to a relatively stable part of the breathing cycle. The chasing technique creates a static target by aligning the intervention device dynamically with the tumour's changing position. Although these techniques show promising results in radiotherapy, they have not been applied to other procedures where respiratory motion causes displacement problems.

The goal of this thesis is to present a conceptual design of a needle insertion device (NID) that is able to respond to- and compensate for breathing-induced lesion motion located inside the liver. Since the liver is located directly beneath the diaphragm, it is strongly influenced by respiration. In the following we will therefore focus on the liver and lesions within the liver as an exemplary site that is subject to extensive respiratory motion. In order to compensate for the motion, the NID will combine two motion management techniques; gating and chasing. In

the moment leading up to- and during the expiratory pause the NID will move in alignment with the lesion. The NID will also advice the medical professional on the optimal moment of insertion. The insertion itself will be automatic.

The rest of the report is organized as follows. In chapter 2, the respiratory motion and it 's management techniques will be studied and described. Chapter 3 describes a more detailed problem description and the proposed solution. Chapter 4 describes a small literary review and pre-concepts of the mechanical features of the NID. In chapter 5 the final design of the NID is presented. The control theory is explained in chapter 6. Capther 7 shows the final design of the NID, it also checks if all the requirements are met. The discussion is presented in chapter 8 and the conclusion 9.

2 Background

Respiratory organ motion is a complicating factor in many treatments. This introductory chapter provides an overview over respiratory induced motion, the current techniques for managing this motion and the resulting issues in accurate needle placement. Additionally, the state-of-the-art needle insertion devices (NID) are described and the organisation of the report is outlined.

2.1 Respiratory Motion

Human respiration is the exchange of air between the lungs and the environment and can be described as quasi-periodic motion between inhalation and exhalation.[7] For inhalation, the diaphragm actively contracts and pushes the contents of the abdomen in inferior direction. At the same time the external intercostal muscles expand the rib cage. For exhalation, the diaphragm and the external intercostal muscles relax. Thereby the volume of the rib cage decreases and the abdominal organs can move in superior direction again. Additionally, active exhalation can be performed by contracting the abdominal and the internal intercostal muscles.[7; 6] A simplified presentation of breathing process described above can be seen in Figure 2.1. In Figure 2.2a an exemplary breathing curve that illustrates the superior-inferior motion of the diaphragm is shown. The graph shows that at maximum inhalation the breathing almost immediately turns from inhalation to exhalation. At maximum exhalation however, there is a small resting period before switching back to inhalation. This asymmetry in the breathing cycle was observed in numerous works and led to a widely adopted respiratory-motion-model.[8]

$$x(t) = x_0 + A * cos^{2n}(\frac{\pi t}{T} - \phi_0) \tag{2.1}$$

Equation 2.1 describes the one-dementional motion over time t where A is the peak-to-peak amplitude, T is the breathing period, x_0 the starting position and ϕ_0 the starting phase. The typical respiratory rate for a healthy adult is about 12-18 cycles per minute (cpm), fluctuating depending on a number of factors including current state of mind.[9] The model was also found to be a suitable approximation for the trajectories of lung tumours and could therefore be used in this thesis to simulate lesion motion.[10]

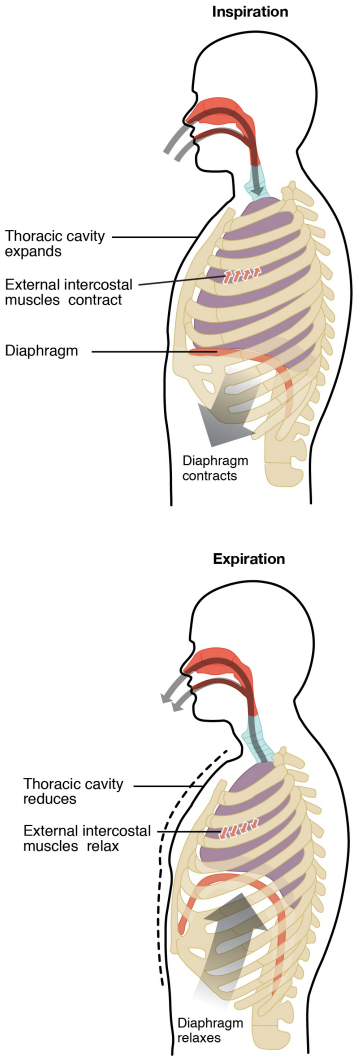


Figure 2.1: Respiratory motion. a) Inhalation. b) Exhalation.[6]

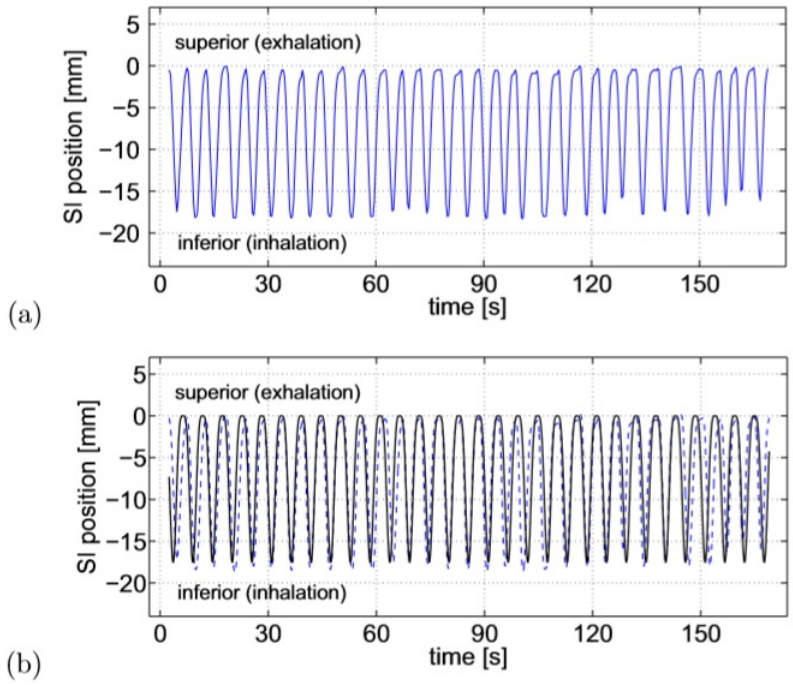


Figure 2.2: Superior-inferior motion of the diaphragm. a) Regular breathing cycle. b) Respiratory motion model of the same cycle.

Figure 2.2b) shows an overlay of the model described in Equation 2.1 and the exemplary breathing curve from Figure 2.2a).

Since respiration is mainly driven by the diaphragm, the motion is predominantly in superior-inferior direction. The diaphragm typically shows a superior-inferior motion of 10-30mm during quiet breathing.[11] Closely adjacent structures show comparable amplitudes (see Table 2.1). Besides the proximity to the diaphragm, the fixation to surrounding tissue is an important factor for the mobility of organs.[7]

Table 2.1: Induced motion.

Organ	displacement
Diaphragm	10 - 30mm [11]
Liver	5 - 25mm[12]
Kidney	1 - 25mm [13]
Lung	3 - 12mm [10]
Spleen	1 - 13mm [13]
Heart	2.4 - 7.9mm [11]

2.2 Motion Management

The average respiratory-induced motion shown in table 2.1 displays the importance of motion management techniques. In the upcoming section some of these techniques are highlighted.

2.2.1 Breath-hold

An evident method to avoid respiratory motion is to completely interrupt breathing whilst the needle is inserted. Over the years different breath-hold methods have been created. These methods can be divided in two groups; forced vs. voluntary breath-hold.

The most used form of forced breath-hold is the spirometry-based active breathing controller (ABC).[14] In this approach, the patient breathes through a valve that can be opened and closed depending on the respiratory signal determined by the spirometer. The valve prevents the patient from exhaling or inhaling outside the required threshold, creating a more stable/constant breathing cycle. As the spirometer is connected to a computer, the clinicians are also able to visualise the patient's level of inspiration.[7; 14]

A widely used form of voluntary breath-hold is deep inspiration breath-hold (DIBH).[7; 15] During DIBH, patients must take a deep breath, and hold this breath in order to prevent the lesion from moving during treatment. DIBH is mostly used during radiation therapy.[7; 14; 15]

Since holding one's breath and following the respective instructions requires a considerable amount of patient cooperation a new motion management techniques had to be created.

2.2.2 Motion Gating

Instead of relying on the patient to maintain a certain target position, the medical intervention can be restricted to a relatively stable part of the spontaneous breathing cycle. This technique is called *respiratory gating*. Gated treatment offers reduced respiratory motion with less patient effort.[16]

Respiratory gating was first published by Ohara et al. in 1989.[7; 15] It was developed for procedures which involve tumours that were unable to remain stable due to respiration. In the last ten years, gating has become part of the clinical routine at a growing number of institutions.[7; 16] In respiratory-gated treatment, a device external to the patient monitors breathing and allows medical intervention only during certain time intervals, synchronous with the patient's respiratory cycle.

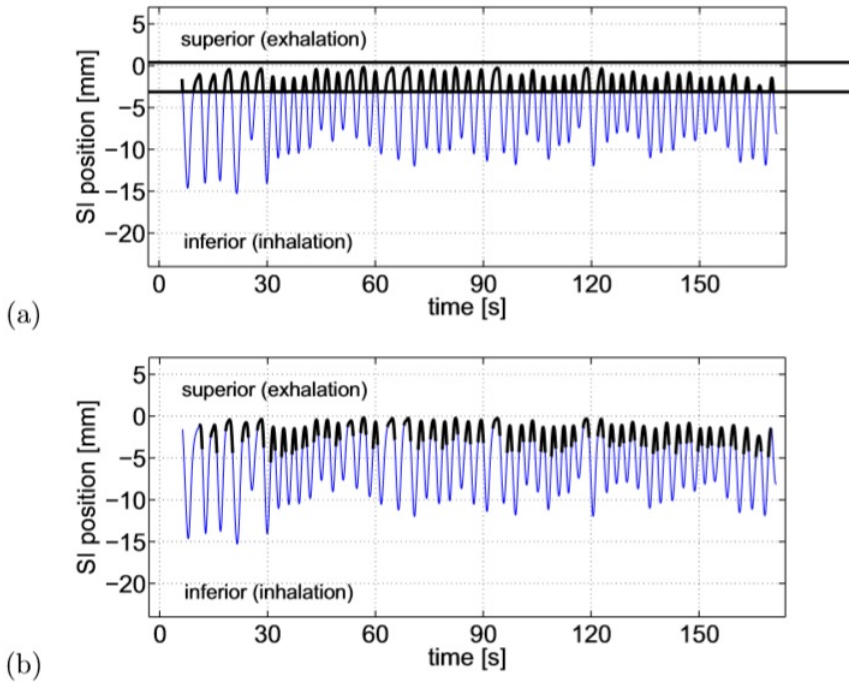


Figure 2.3: a) Displacement- and b) Phase gating within the breathing cycle.[7]

Since respiratory motion can be characterized by two variables that are recorded as part of the respiration signal or the motion of the internal anatomy, two types of gating methods exist. These variables are *displacement* and *phase*.[17] Accordingly, the method of gating is referred to as either displacement gating or phase gating.

The displacement of the respiration signal measures its relative position between two extremes of breathing motion, namely, inhalation and exhalation. In displacement-based gating, the medical intervention is preformed whenever the respiration signal is within a pre-set window of relative positions.[7; 17] A visual representation of displacement gating within the breathing cycle can be seen in Figure 2.3a.

The second variable, phase, is calculated by an algorithm from the respiration signal that must satisfy periodicity criteria. the medical intervention is preformed when the phase of the respiration signal is within a pre-set phase window. Figure 2.3b shows a visual representation of phase gating within the breathing cycle. Typically, a gate extends over a region of the breathing cycle where the motion of the tumour is estimated to be less. During free breathing, the inhalation position typically shows a larger variability than the exhalation position.[10] However, gating at inhalation, where the chest expansion can lead to a better separation and lesser density of lung tissue, can be advantageous in some applications.[7] The small amount of tumour motion that still occurs within the gate is referred to as *residual motion*.[17]

2.2.3 Motion Chasing

Another effective way of managing respiratory motion is to align the intervention device dynamically with the tumour's changing position in order to obtain a static target. This technique is referred to as real-time *tumour chasing*.[7; 17] Two different chasing methods are currently either under development or clinically available. The first method to keep the target and the intervention device aligned, is to move the intervention device simultaneously with the target motion. An alternative approach is to move the treatment couch and keep the device in a fixed position.[18] To succeed, this chasing technique should be able to satisfy three requirements; identify the tumour position in real time, anticipate the tumour motion to allow for time delays in the response of the positioning system; and reposition the system along with the tumour position.[17]

Detecting the tumour position is the most important and challenging task in real-time chasing. Currently, there are four possible means of locating the tumour during treatment: 1)Imaging of the tumour itself 2) imaging of fiducial markers implanted in the tumour; 3)inference of the tumour position from surrogate breathing motion signals; and 4) non-radiographic tracking of an active or passive signalling device implanted in the tumour.[17]

An important advantage of gating and chasing is that they both require only minimal patient cooperation and can be applied during free, natural breathing. However, both methods work most accurately if the respiratory motion is as regular as possible.[7]

Currently, the motion management techniques mentioned above are mainly used in/during radiation therapy.[7; 14; 15] However, they could also be applied to other kinds of procedures where respiratory motion causes displacement problems. An example of such is minimally invasive needle insertions. During such procedure a needle in inserted through the skin, towards a target.

2.3 Medical Needles

Medical needles are common devices used in percutaneous procedures.[19] Several parameters that affect needle and tissue interaction have been identified and include needle geometric properties, such as tip shape, diameter, and length, needle insertion velocity, motion profile and tissue elastic properties.[20] The function of the needle tip is to create a passage through tissue. This is typically achieved by a combination of cutting and wedging. The amount of force needed to cut a path, and the amount of tissue damage that arises as a result, depend on the shape of the needle tip.[19] The most common needle tip shapes are depicted in Figure 2.4. The needle diameter is expressed using the Wire Gauge (G) System and standard

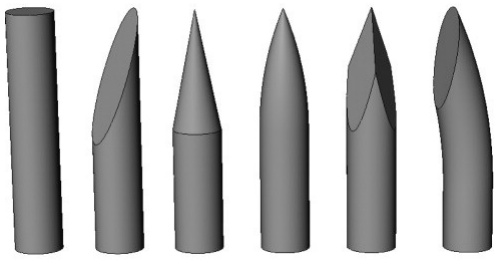


Figure 2.4: Basic needle tip shapes (left-to-right): blunt, beveled, conical, Sprotte, Franseen and Tuohy.[19]

sizes range from 10G (3.4mm) to 35G (0.2mm).[19] Okamura et al. investigated the effect of needle diameter and tip type on insertion forces.[21] They found a significant effect of tip type on insertion forces. Insertion forces increased as the needle tip type changed from triangular to bevel and bevel to cone. They also found that for each of the tip types, the increase of needle diameter increased the insertion force. Varying the needle bevel angle from 8°to 82°results in the insertion force increasing monotonically, while the needle deflection does not.[20] Experimental results indicate that higher needle insertion velocity reduces deformation and insertion force.[4] However, only robots can use high needle insertion speeds safely. Manual insertion requires lower speeds.[4]

2.4 Robot-Assisted Needle Insertion

To date, a number of researchers have explored ways to improve the process of needle insertion in soft tissue using robotics and medical imaging in order to improve the accuracy of the procedure. Robot-assisted needle insertion can overcome the previously mentioned limitations and increase the success rate of many procedures.[22] The main idea behind robotization of percutaneous procedures is not to replace the medical professional but to modify the workflow, with certain acts performed by a robotic assistance which could be either automatic or teleoperated. The robotic assistants aim at replicating the two most important acts, namely needle positioning and needle insertion while responding to respiration movement and avoiding sensitive structures.

Multiple needle insertion devices (NID) are currently either under development or clinically available. The classification of these needle insertion devices can either be based on their architecture or based on the fixation of the device in the operating room.[23] When classified based on architecture; NID can either have a serial, parallel or hybrid architecture. When classified based on their fixation, the NID can be a Table Mounded Systems (TMS) or a Patient Mounted Systems (PMS). Representative examples of TMS and PMS systems are shown in Figure 2.5, respectively.[25; 24]

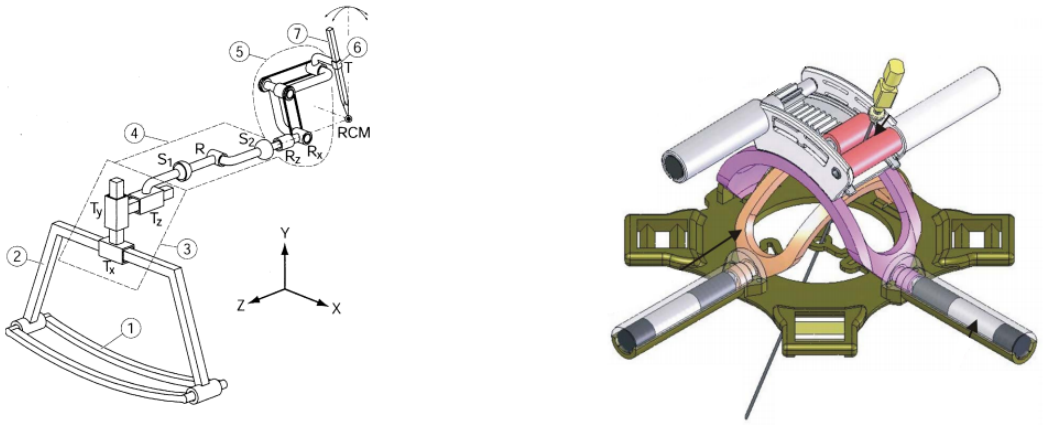


Figure 2.5: a) Acubot, a table mounted NID with serial architecture.[24] b) Robopsy, a patient mounted NID with parallel architecture.[25]

TMS are generally of serial architecture and therefore can have large orientation and translational workspace, extra degrees of freedom (DOF) without much regard for compactness. On the downside they are generally with higher inertia, weight and without compensation for movement of the patients body surface. Hence, they can pose safety issues in case of sudden involuntary motion by the patient. On the other hand PMS are compact, portable allow to partially compensate for patient motion and have parallel architecture. Hence, PMS are intrinsically safer. Owing to the primarily parallel structure, PMS have relatively smaller workspace and have to deal with the problem of singularity free workspace. With higher DOF and actuators on-board, size and weight of the NID increases considerably.[23]

3 Analysis

Since the liver is located directly beneath the diaphragm, it is strongly influenced by respiration. In the following we will therefore focus on the liver and lesions within the liver as an exemplary site that is subject to extensive respiratory motion. However, the developed techniques can be applied to any organ or target affected by respiratory motion.

3.1 Liver Motion

The liver is the largest internal organ in the human body and carries out a range of essential tasks such as detoxification, protein synthesis and the production of chemicals necessary for digestion. The liver is located just below the diaphragm on the upper-right side of the body. [7] The shape of the liver is mainly determined by the surrounding structures and therefore shows large variations in size and shape between subjects, as can be seen in Figure 3.1.[26]

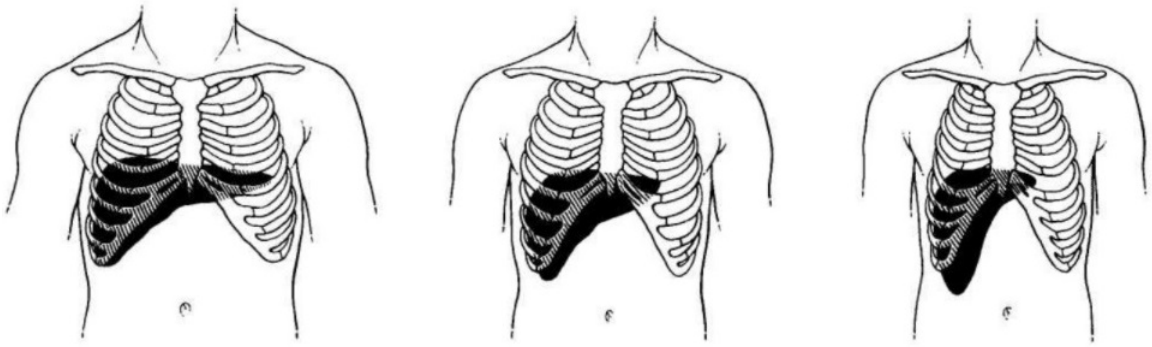


Figure 3.1: Frontal views of the liver showing the various sizes and shapes it can assume.[27]

Since the liver is located directly beneath the diaphragm, it is strongly influenced by respiration. The main component of this motion is a superior-inferior shift, typically in the range of 5-25mm for relaxed breathing.[12] The liver additionally shows motion in anterior-posterior (1-12mm) and left-right direction (1-3mm) as well as non-rigid deformations. For lesions in the liver, Kitamura et al. showed that the extent of motion depends to a certain degree on the position in the liver, on cirrhosis, and on the surgical history. [28]

In addition to the observed difference in duration (shown in Figure 2.2b), the respiratory motion also follows a different trajectory during inhalation and exhalation. Figure 7.1a shows the typical elliptic shape of such a trajectory in the sagittal plane for a point in the liver near the diaphragm.[7]

3.2 Design Goal

The goal of this report is to present a conceptual design of an NID that is able to respond to- and compensate for breathing-induced lesion motion located inside the liver. In order to compensate for the motion, the NID will combine two motion management techniques; gating and chasing as explained in the following.

At first, the current tumour location, and thus the entry point on the skin, must be determined. Since the liver is located just below the diaphragm on the upper-right side of the body, its mostly covert by the ribcage.[7] In order to make sure no sensitive structures are hit during insertion, a pre-selected entry point needs to be appointed. The needle is initially placed with its tip at this entry point and then oriented about that pivot point for target alignment. This pivot point is called the remote centre of motion (RCM). By monitoring the patient respiratory phase

in real time using the respiratory gating system, the NID will advice the medical professional on the correct insertion moment. Once the medical professional decides to insert, the robot manipulator will quickly advance the needle along the planned needle path towards the targeted meeting location with the lesion within the chosen respiratory window. As described previously; gating is a respiratory motion management technique that restricts the medical intervention to a relatively stable part of the spontaneous breathing cycle. As illustrated in Figure 3.2, during the *expiratory pause* the tumour is mostly stationary. During relaxed breathing, the expiratory pause last for about 0.5 seconds. Inserting the needle within this pause would be ideal. After the needle tip reaches the desired depth, the non-inserted part of the needle requires to be released from the NID in order to comply with the motion exerted by the internal perforated organs and thereby avoid further tissue lacerations. At this stage the needle should move freely off a central position about the entry point on the patient's skin.

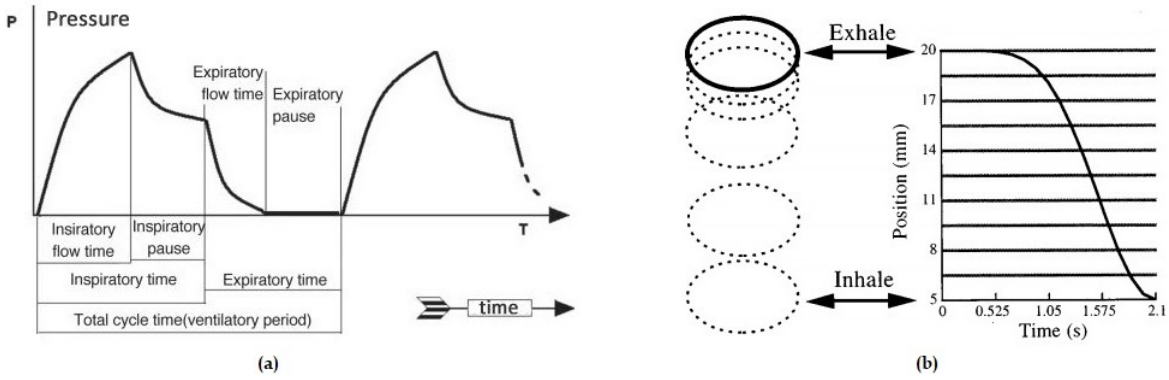


Figure 3.2: a) Phases of the respiratory cycle.[29] b) Lesion position as a function of time, discretized into 10 bins for one half of a breathing cycle.[8]

3.3 Stakeholders

When designing a new product different stakeholders are involved. Stakeholders are defined as individuals or organizations who stand to gain or lose from the success or failure of a system.[30] Traditionally it's the needs of three main stakeholder groups which must be considered when developing a new medical device; those of the patient, the provider and the payer. Each has needs and expectations of the final device so it is vital to accurately represent these requirements and factor them in early on to ensure successful product development and final design.[31]

3.4 Assumptions

When designing a new product, some assumptions have to be made. Assumptions are statements that the designer will not spend time or effort in considering. These statements will simply be accepted as facts.

- **The real-time tumour location will be known to the NID.** The NID should be capable of positioning the needle in alignment with the moving tumour. The positioning system is based on the current tumour position as well as a predictive algorithm in order to anticipate the tumour motion to allow for time delays in the response of the positioning system and needle insertion. Medical imaging (ultrasound (US), computed tomography (CT) and magnetic resonance imaging (MRI)) plays an important role in determining the current tumour location. Several studies and clinical practices show that off-line medical imaging does not provide enough accuracy for precise procedures.[3] Therefore, real-time imaging techniques are preferred.

- **The needle insertion causes no tissue deformation.** The NID will be able to insert the needle at high velocities (+-300 mm/s). Experimental results indicate that higher needle insertion velocity reduces tissue deformation and insertion force.[4]
- **The needle shows no signs of deflection.** Needles have variable shapes and diameters with different flexibility and manoeuvrability. Needles can be categorized into two groups: rigid and flexible needles. Needle is rigid when remains stiff after insertion, or flexible when deflects with small transverse forces. In this thesis a 154 x 2.1 mm biopsy needle will be used. This needle is considered as rigid and therefore needle deflection is negligible.[4]
- **The *target* in this thesis is described as a 15 mm lesion located 100 mm beneath the skin.**

3.5 Requirements

The robot must satisfy the following requirements.

The Needle Insertion Device needs to ..

.. **have a maximum insertion length of 120 mm.** By percussion, the mean liver size is 70 mm for women and 105 mm for men.[27] With an insertion length of 120 mm, the device should be able to reach all possible tumour sites.

.. **cover a range of 50 mm for target respiratory motion.** For relaxed breathing, the liver has a superior-inferior motion range of 5-25mm.[12] With an motion range of 50 mm, the device should be able to reach all possible tumour sites.

.. **have a fixed entry point.** Since the liver is located just below the diaphragm on the upper-right side of the body, its mostly covert by the ribcage.[7] In order to make sure no sensitive structures are hit during insertion, a pre-selected entry point needs to be appointed. The needle is initially placed with its tip at this entry point and then oriented about that pivot point for target alignment.

.. **have at least two DOFs.** One DOF is needed for keeping the needle in alignment with the target, the other DOF is needed to move the needle trough the tissue towards the target.

.. **have a maximum error of 3 mm.** The target is described as the centre of the lesion. A lesion is considered malignant when it's >10 mm.[32] With a 3 mm accuracy deviation the NID is still capable of reaching the target properly.

.. **have an insertion speed between 240-300 mm/s.** The average expiratory pause of a human adult last for 0.5 seconds.[9] Since the needle should reach the target within this period, it should be travelling at least 240 mm/s.

.. **comply with existing surgical needles.** It would be beneficial to the NID to comply with existing surgical needles, in terms of diameter and length, and thus avoid the use of device specific needles.

.. **be sterile.** The NID and all of its components must be sterilized before they can be used in the operating room. In such a case, modular design can be favourable in order to make some components disposable or reusable after sterilization.

.. **be safe in use.** The NID should not cause any tissue lacerations other than straight trajectory insertion.

3.6 Functions

While fulfilling the requirements, the NID must be able to perform the following functionalities;

- **Needle Positioning/Alignment.** The NID should be capable of positioning the needle in alignment with the moving tumour. The positioning system is based on the current tumour position as well as a predictive algorithm in order to anticipate the tumour motion to allow for time delays in the response of the positioning system and needle insertion.
- **Needle Insertion.** The NID should have an semi-automatic insertion mechanism. The mechanism responds to the current tumour location and adjust the insertion depth accordingly. The insertion itself is activated by the surgeon since they is aware of the total situation and are therefore able to select the best insertion moment.
- **Needle Release.** The NID should be able to release the needle once inserted. This is required, in particular, to prevent tissue lacerations due to physiological motions.
- **Insertion Aid.** The NID should advice the medical professional about the best insertion moment. This moment can be selected via the gating method described previously.

4 Design Description

The NID described in the section 3.2 can be divided into four different sections; chasing, inserting, releasing and advising.

4.1 Lesion Chasing

As the NID requires a fixed entry point the chasing paths are limited. An evident option is circular chasing motion with fixed radius. In 3D, spherical mechanisms are widely used in many robotic and positioning systems where an arm or instrument is orientated in pitch and yaw angles.[25] Dien et al. described using two independent slotted spherical yokes, which can position a pin that rides in both hoops so that it described a near complete hemispherical workspace (Figure 4.1a).[33] Stanisic et al. combined two of these "pointing" mechanisms back to back, such that they can serve as a joint, between two intersecting arms, which is capable of producing singularity free motion (Figure 4.1b).[34]

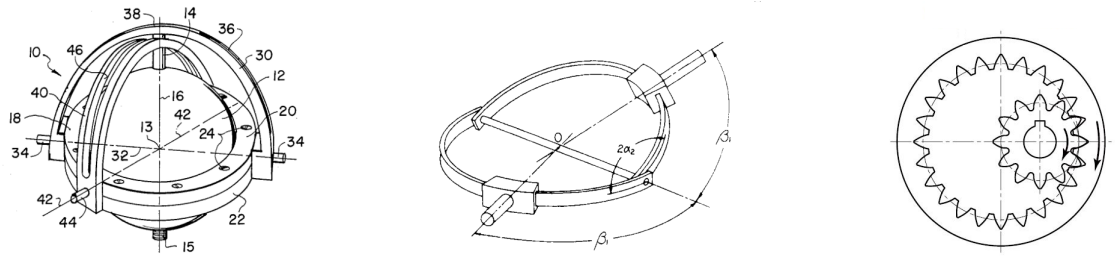


Figure 4.1: Positioning system sketch designed by (a) Dien et al.[33] and (b) Stanisic et al.[34]. c) Internal Spur Gear.

The internal spur gear with motorized pinion illustrated in Figure 4.1c will be the main motion generator for the NID. The pinion will stay in place while the internal gear will rotate around this pinion. The needle will be placed on top of the internal gear. With the needle tip positioned at the centre of the internal gear, a fixed entry point is generated.

4.2 Needle Insertion

The insertion tool is a critical part of the overall robotic needle insertion device. It needs to hold the needle in place, insert the needle with sufficient speed and release the needle once inserted. After a survay in the literature, several systems dedicated to needle grasping and insertion could be identified. Piccin et al. created an insertion device based on helical gears and screw mechanisms.[35] In the work of Hungr et al., rail and ball screw along with a rotary brushless DC servo motors were used for the insertion mechanism and its actuation.[36] Mechanism with belt and pulley system actuated by piezomotors were used for the insertion mechanism in the work of Seifabadi et al.[37]. A mechanism based on linkages with a prismatic and revolute joints was used in the work of Badaan et al.[38]. The most frequent working principle involves opposing rollers to perform simultaneously needle grasping as well as its insertion motion.[35; 23]

For the needle insertion two options have been explored in further detail, namely opposing rollers and gearrack & pinion systems. The opposing rollers are used in various robotic devices and therefore seem to be an ideal mechanism for needle insertion(Figure 4.2a). However, axial insertion force measurement turns out to be very difficult or even impossible with this principle since the force measurement highly depends on friction conditions with the needle barrel. This system can also introduce inaccuracies due to the flexibility of the rollers and slippage of the needle. Replacing the needle and rollers by gearracks & pinions could resolve these problems (Figure 4.2b).

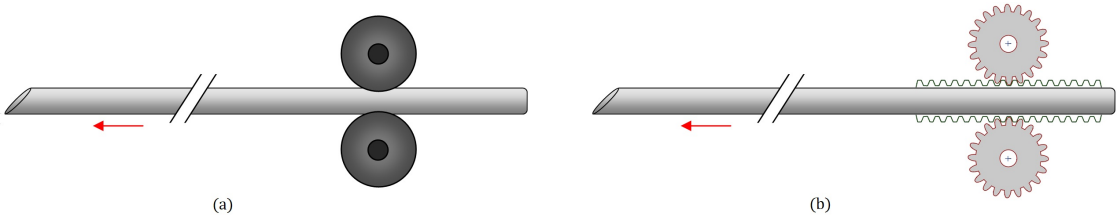


Figure 4.2: Insertion mechanism based on (a) the posing rollers principle, (b) gearracks & pinions.

4.3 Needle Release

After the needle tip reaches the desired depth, the non-inserted part of the needle requires to be released from the NID in order to comply with the motion exerted by the internal perforated organs and thereby avoid further tissue lacerations. Among the studied relevant designs related to NID, this had rarely been addressed. Passive needle release would be preferred over active release since is doesn't require an extra motor, which means less weight. For needle release, three ideas were constructed as explained in the following.

Concept l is suitable when the insertion mechanism is based on an opposing rollers principle that simultaneously combines grasping with insertion. At the desired depth, the NID is simply unable to insert the needle any further because the needle and NID are no longer in contact. Figure 4.3 shows such a release mechanism.

Figure 4.3: Concept l applied to the opposing rollers principle (a) during insertion, (b) once the desired depth is reached.

An advantage of this concept is that slippage is no longer an issue. The rollers simply keep spinning until there is no longer contact between the needle and roller. The disadvantage however, is that the depth depends on the needles placement between the rollers.

When automatic needle extraction as well as insertion is required, the NID should be able to regrasp the needle. **Concept ll** solves the problem of releasing and regrasping by having the needle move inside a shell with a flexible segment (Figure 4.4). Here, the needle isn't fully released but still capable of moving 'freely'off a central position about the entry point on the patient's skin. The needle (shown in red) is pushed forward through the shell (shown in grey) by a similar sized, circular bar (shown in blue). Once fully inserted, the end of the needle will reach the flexible part of the shell, giving it the ability to move in all directions. Since the bar and needle are attached by a small wire, the needle can simply be extracted by retracting the bar. The retracting can be done by rotating the opposing rollers in the opposite direction.

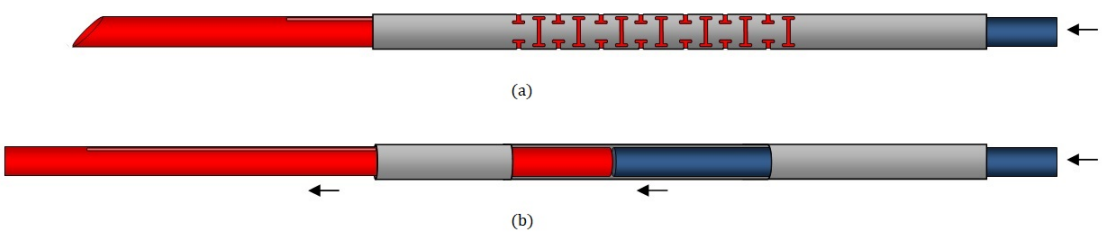


Figure 4.4: Concept ll, flexible needle cover.

Concept lll is similar to concept ll. Here, the needle is also covered by a shell and stays partly attached to the NID (Figure 4.5). During insertion needle and shell move as a whole, once the desired depth is reached the shell retracts exposing the flexible needle part.

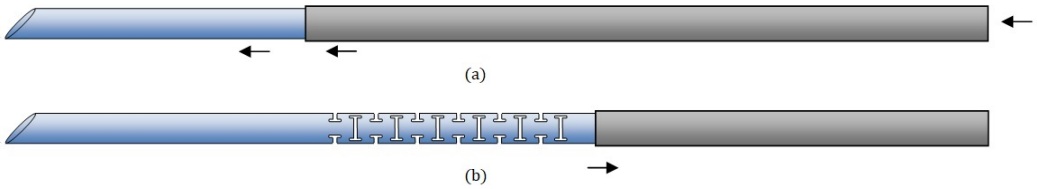


Figure 4.5: Concept lll, flexible needle segment.

A major drawback of concept ll and lll is that, once inserted, the end of the needle is not accessible, making biopsies impossible. On top of that, literature shows low interest in automatic needle extraction.

4.4 Insertion Aid

Once the needle is correctly placed with its tip at this entry point and then oriented about that pivot point for target alignment, the best insertion moment can be selected. By monitoring the patient respiratory phase in real time using the respiratory gating system, the NID will advice the medical professional on the correct insertion moment. Figure 4.6 shows the lesion position as a function of time for one half of the breathing cycle. It illutrates that during the expiratory pause the tumour is mostly stationary. The NID will indicate that the expiratory pause is approaching and when to insert. The indication can be realized by small coloured LEDs (red; do not insert, orange; get ready to insert, and green; INSERT). The LEDs can be attached to the NID or located elsewhere in the operating room.

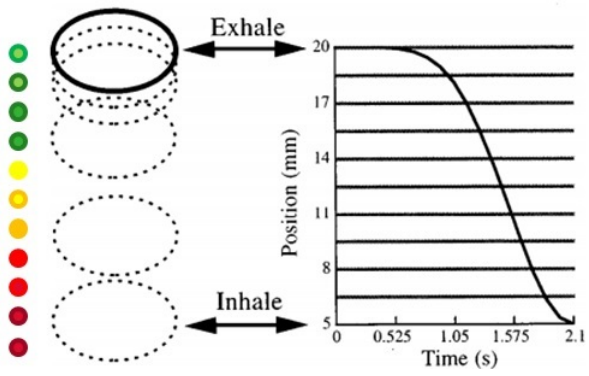


Figure 4.6: Lesion position as a function of time, discretized into 10 bins for one half of a breathing cycle with insertion advising LEDs.[8]

5 Design

The needle insertion robot for compensation of lesion motion can be divided into four different components. The first two are the chasing- and insertion component. The last two are the release mechanism and the insertion aid which advices the medical professional on the best moment of insertion.

5.1 Tumour Chasing

As described previously, the main motion of the NID is realized by an internal gear and motorized pinion (Figure 4.1c). Since the NIDs movement only covers a small part of the circular path, using only a part of the internal gear should suffice.

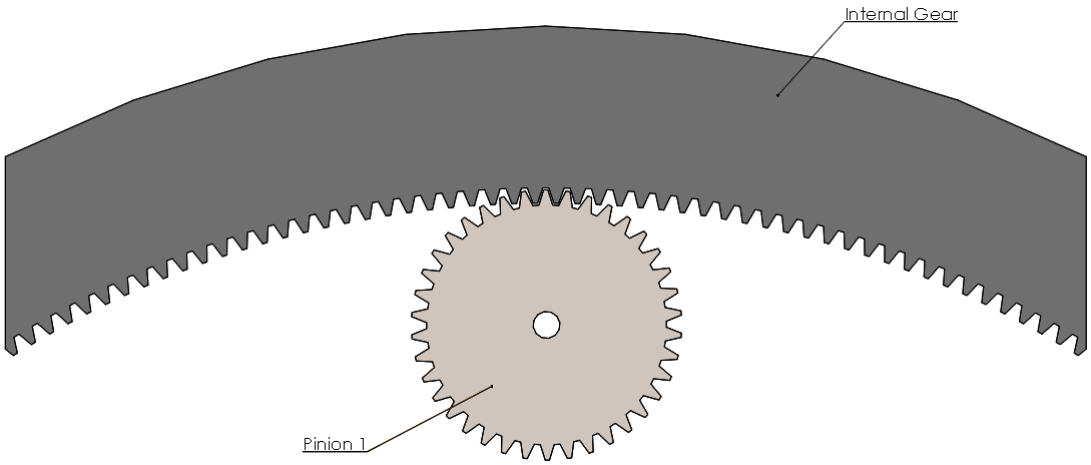


Figure 5.1: Internal gear and motorized pinion in 2D.

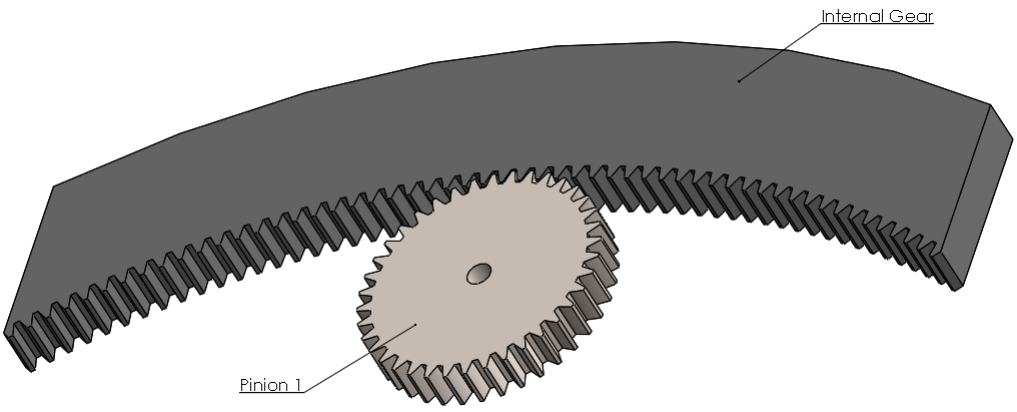


Figure 5.2: Internal gear and motorized pinion in 3D.

As gears can't float, a base that holds the components needed to be constructed (Figure 5.3) In order to obtain close contact between the internal gear and pinion, two small wheels have been added. The wheels are completely passive and also function as a guide for the rotational motion of the internal gear. A transparent cover has been added to prevent any tilting motion, as the weight of the insertion tool might cause the internal gear to lean forwards.

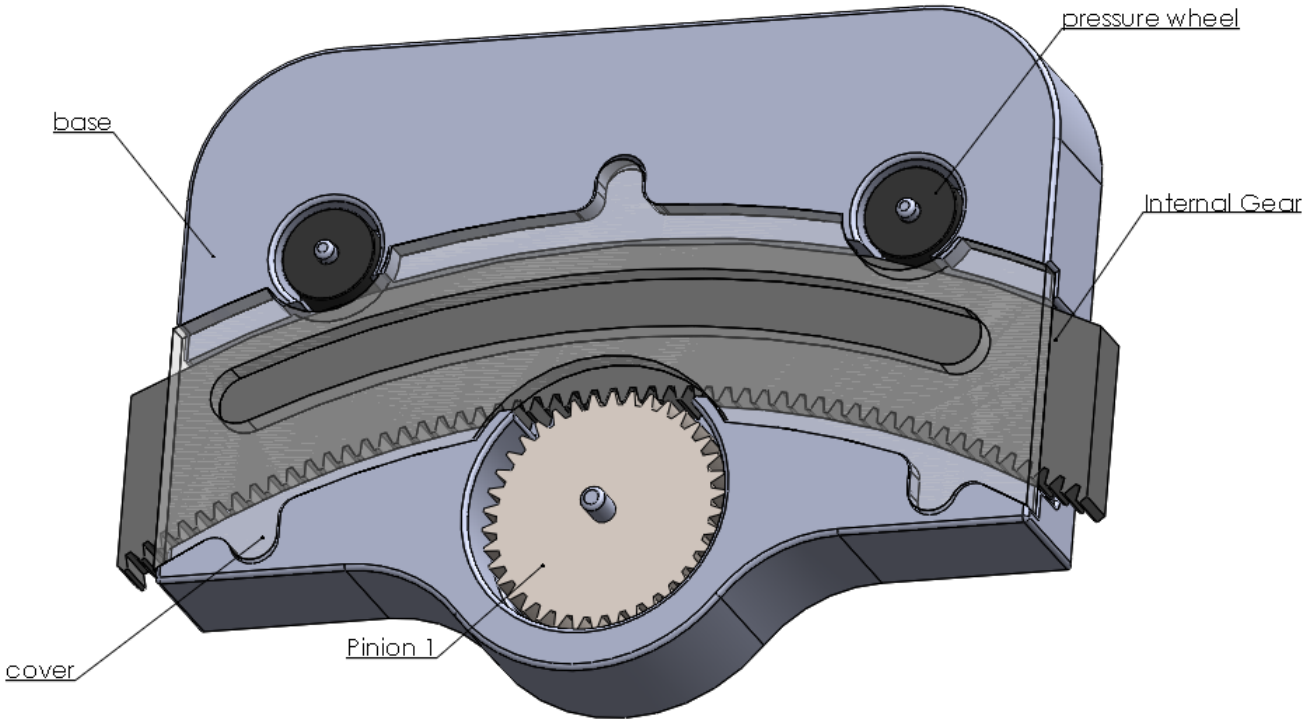


Figure 5.3: The base block with chasing components.

Friction could prevent the NID form operating smoothly. In order to solve the possible friction issue, the internal gear and base are made from a material called Polyoxymethylene (POM). POM also known as acetal, polyacetal, and polyformaldehyde, is an engineering thermoplastic used in precision parts requiring high stiffness, low friction, and excellent dimensional stability.[39]

5.2 Needle Insertion

The insertion component is attached to the internal gear via a short rod. The base of the insertion component is shown in Figure 5.4. The base is 60x60 mm and consists of two pinion holders, two guide rails and a slide. The guide rails make sure the needle travels in a straight path. The slide allows the needle to move in any direction once released.

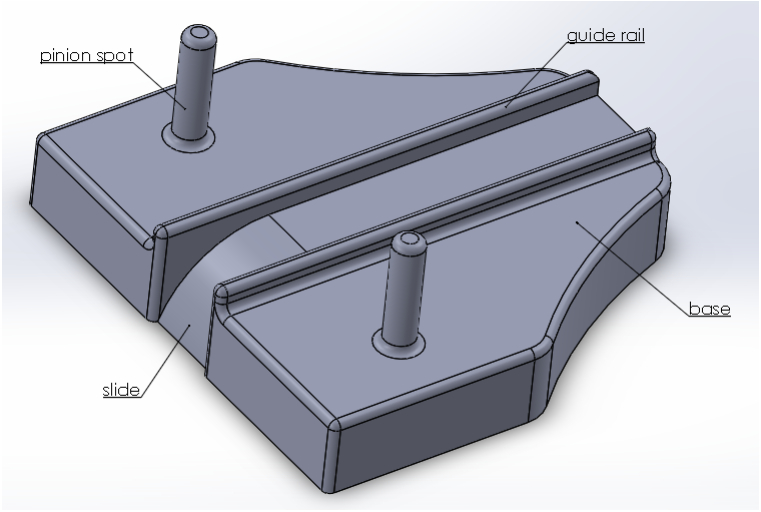


Figure 5.4: Insertion base block, 60x60mm.

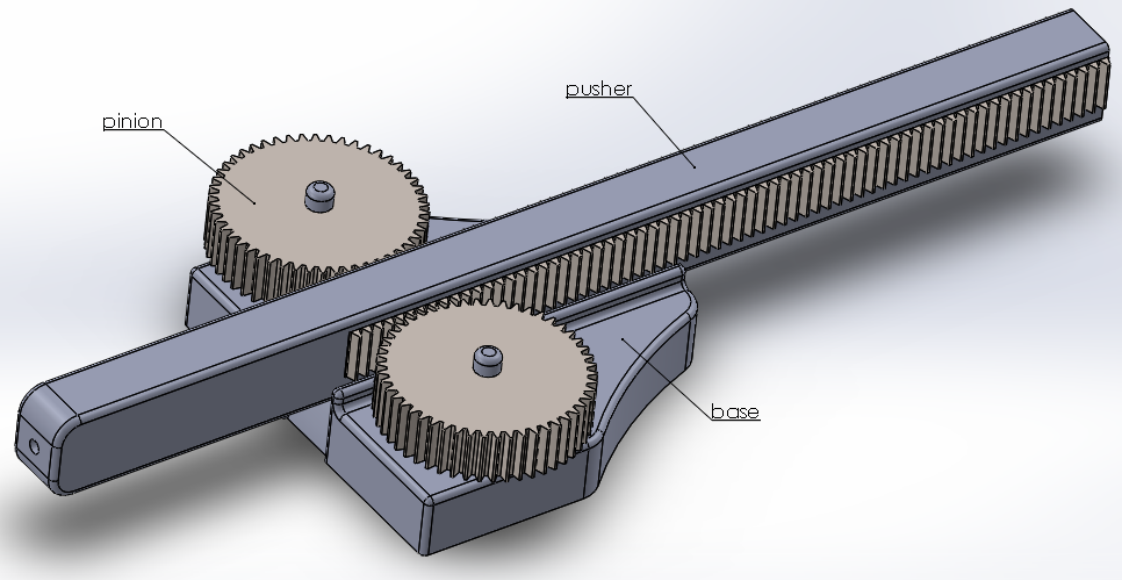


Figure 5.5: Insertion Device.

Figure 5.5 shows the entire insertion mechanism. The pinions and, so-called, *pusher* have been added. The pusher consists of a base, gearrack and needle holder.

5.3 Needle Release

For the release system, concept l is chosen. Once the correct insertion depth is reached, the pusher and pinions should no longer be in contact. This is realized by cutting the square end to inverted circles (Figure 5.6).

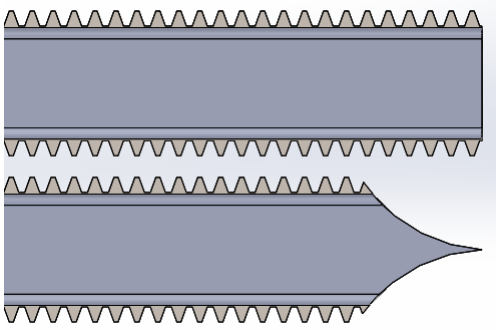


Figure 5.6: The pusher-end, with (bottom) and without (top) release mechanism.

5.4 Insertion Aid

In the previous chapter the insertion aid was described as multiple coloured LEDs. LEDs however, are very small and might become covert by other parts of the device during the chasing process. Therefore, multiple LEDs need to be installed along the base block. For illustration purposes, and as shown in Figure 5.7, a long roller was modelled as representative for a column of LEDs with different colours (green, orange, red). As explained previously, these colours correspond with the insertion time appropriateness.

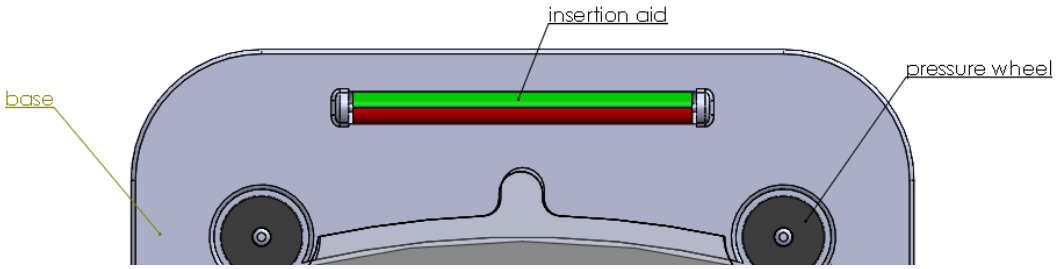


Figure 5.7: Partial image of the NID with its Insertion Aid roller.

5.5 Component List

The components and their specifications are listed in Table 5.1

Table 5.1: NID Component Table.

Component	**Specifications**	No.
Base block	180x110x25 mm	1
Pinion 1	1.25M, 38T, 20PA, 10 FW	1
Motor 1		1
Internal Gear	1.25M, 300T, 20PA, 10FW	1
Pressure wheel	⊘ 19 x 12 mm	2
Cover	perspex	1
Insertion base block	60x60x10 mm	1
Pinion 2	0.6M, 50T, 20PA, 8FW	2
Motor 2		2
Pusher base	120x14x10mm	1
Gear-rack	0.6M, 130L, 20PA, 2.9PH, 8FW	2
Needle	154x2.1 mm	1

6 Control

6.1 Tumour Chasing

The needle insertion system is placed on top of an internal spur gear, which is driven by a smaller motorized pinion. In order to keep the tumour and needle in alignment, the pinion rotation (θ_{p1}) should be related to the current tumour position (x, y). Figure 6.1 shows a visual representation of the mathematics involved. With the known x- and y-position, the radius r_t and angle θ_t can be calculated (Equation 6.1).

$$x = r_t \, cos\, \theta_t \qquad y = r_t \, sin\, \theta_t \tag{6.1a}$$

$$r_t = \sqrt{x^2 + y^2} \qquad \theta_t = tan^{-1}\,(\frac{y}{x}) \tag{6.1b}$$

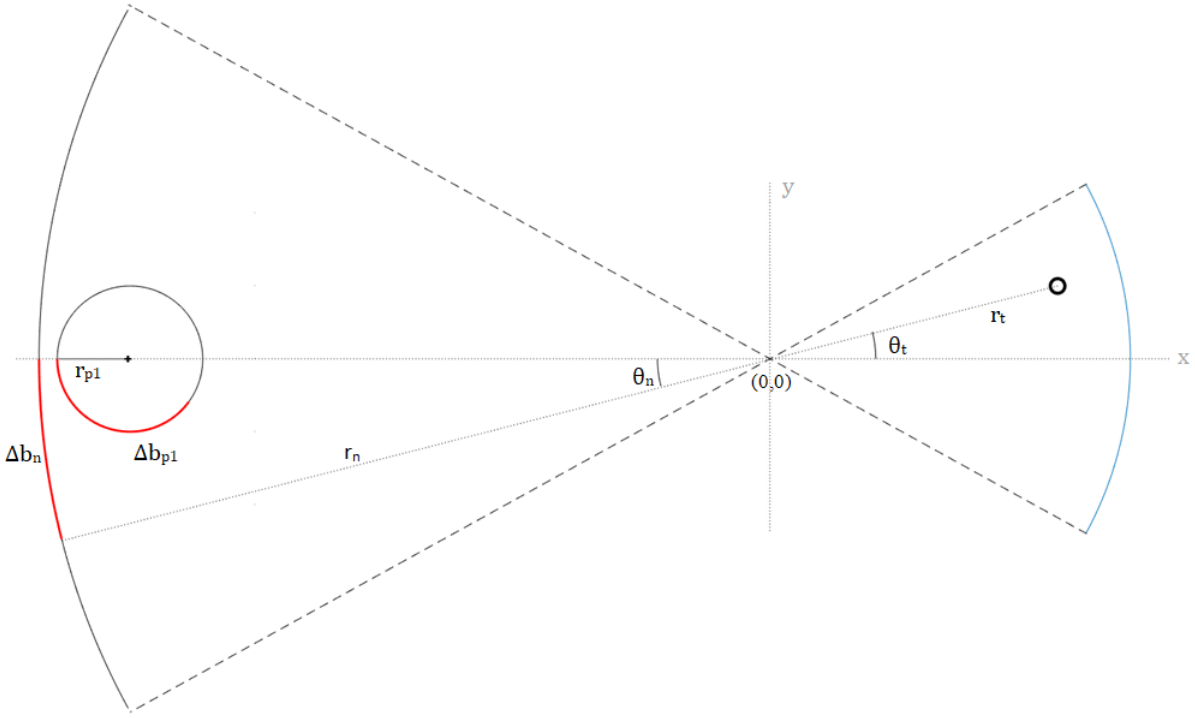


Figure 6.1: Schematic illustration of tumour location and pinion rotation.

$$\theta_t = -\theta_n \qquad \Delta b = \theta * r \tag{6.2a}$$

$$\Delta b_n = \Delta b_p \qquad \theta_n * r_n = \theta_{p1} * r_{p1} \tag{6.2b}$$

$$\theta_{p1} = -\frac{\theta_t * r_n}{r_{p1}} \tag{6.3}$$

The motion of the tumour can be related to the pinion motion using Equation 6.2. Combining Equations 6.1 and 6.2 leads to Equation 6.3 which shows the pinion rotation (θ_{p1}) as function of current tumour position. The radii r_n and r_{p1} are known constants.

$$t = \frac{\Delta l}{v} \tag{6.4}$$

Since needle travelling time must be taken into account, the NID should actually be able to anticipate the tumours motion. The travelling time can be calculated by Equation 6.4, where Δl is the insertion depth and v the insertion speed.

6.2 Needle Insertion

Figure 6.1 illustrated that r_t represents the insertion depth(Δl). The rotational pinion angle is described by θ_{p2} and depends on the insertion depth (Δl), modulus (m) and no. teeth (z) of the pinion (Equation 6.5).

$$\theta_{p2} = \frac{\Delta l * 360}{\pi\, m\, z} \tag{6.5}$$

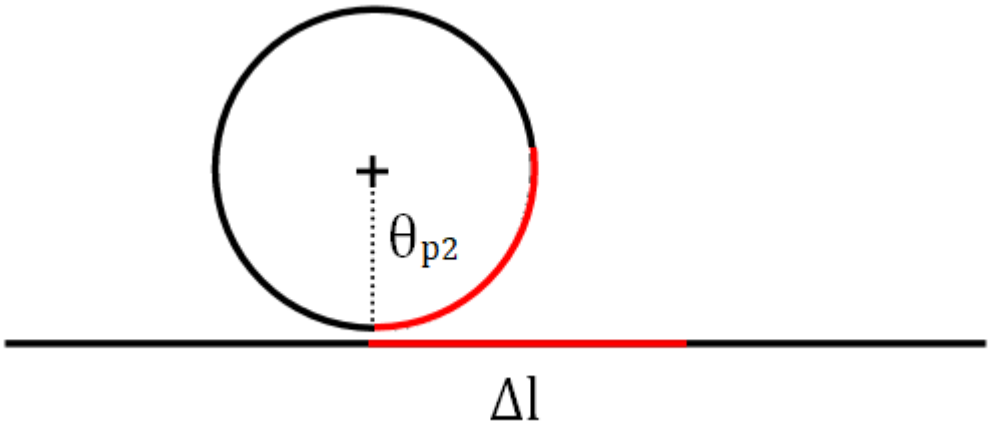


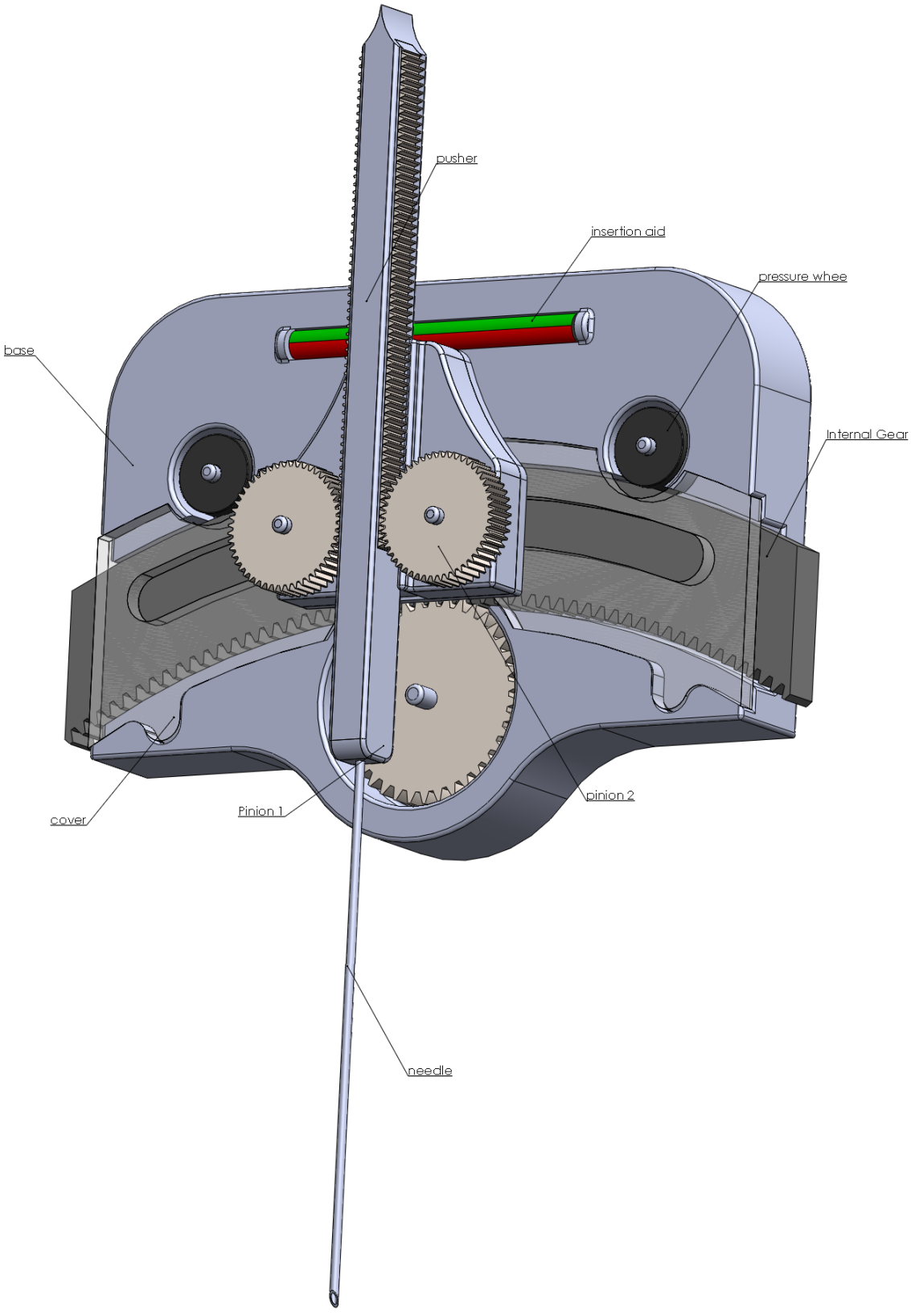
Figure 6.2: Mathematics sketch.

6.3 Path Plannig

The general objective of needle path planning is to determine the optimal needle path for hitting a target and avoiding obstacles. The needle path planning algorithm should aim at optimally planning the needle path according to the respiratory motion model of the lesion and relevant structures/organs. In particular, the needle tip must hit the lesion within the chosen respiratory window.

7 Result

7.1 Final Design



7.2 Proof of Concept

Figure **??**a illustrates the typical elliptic shape of a point in the liver near the diaphragm, measured over 20 breathing-cycles.[7] To test the relationship shown in Equation 6.3 an exemplary tumour path is created in MATLAB (Figure 7.1b). The path consist of 1000 different positions who present themselves within the workspace of the NID (Figure 7.2)

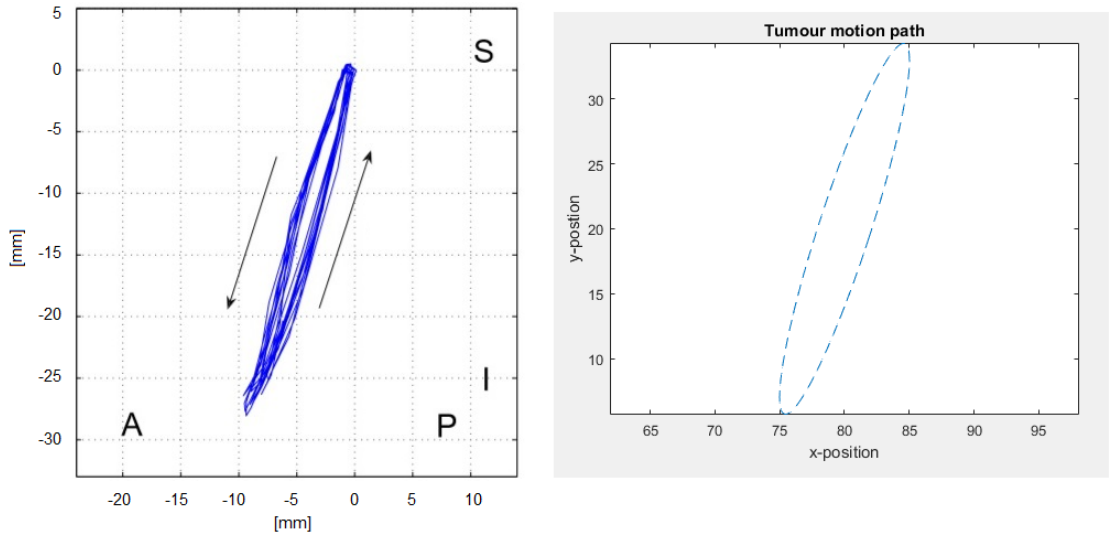


Figure 7.1: (a) Superior-inferior and anterior-posterior motion of an exemplary point in the liver, measured over 20 breathing cycles.[7] (b) Simplified elliptic tumour path.

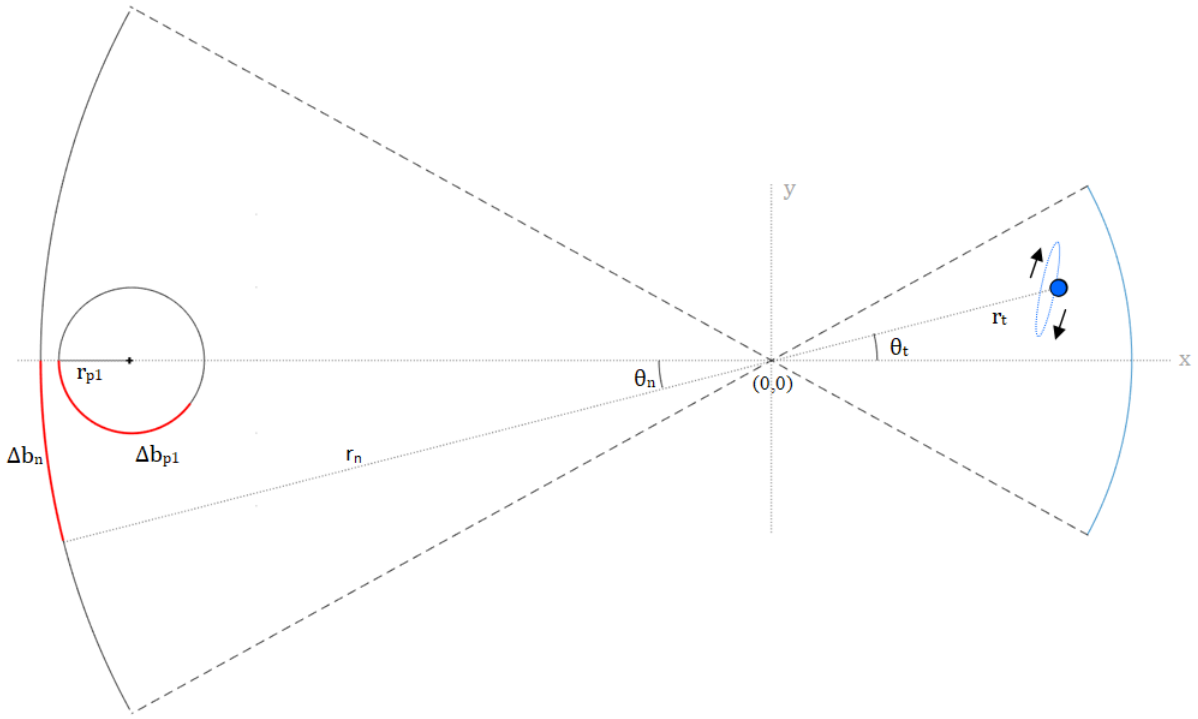


Figure 7.2: Proof of Concept illustration.

By computing the generated tumour locations in the pinion rotation formula (Equationeq:relation) we obtain Figure 7.3. It shows the rotation of the pinion in degrees over the 1000 tumour located that form an elliptic motion path.

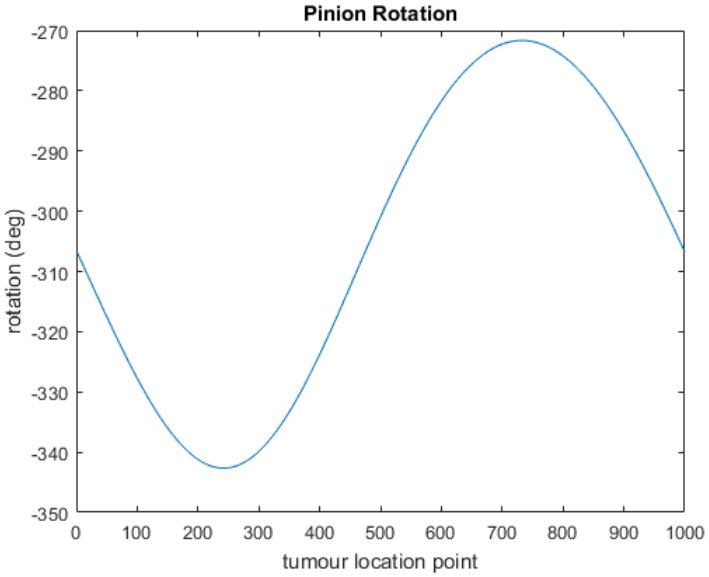


Figure 7.3: The pinion rotation in deg over the 1000 tumour locations.

7.3 Requirements

In order to check if the design goal is met, all the requirements must be fulfilled.

The Needle Insertion Device needs to ..		
..have a maximum insertion length of 120 mm.	OK	The NID is able to insert the needle for 120 mm.
..cover a range of 50 mm for target respiratory motion.	OK	The NID can cover a range of 150 mm target motion.
..have a fixed entry point.	OK	The circular structure of the NID creates a fixed entry point.
..have at least two DOFs.	OK	The NID has two DOFs, chasing rotation and insertion translation.
..have a maximum error of 3 mm.	/	Since the design is not manufactured, this requirement has not been verified.
..have an insertion speed between 240-300 mm/s.	OK	With the correct choice of motors, the insertion speed can be realized.
..comply with existing surgical needles.	OK	The NID is able to comply with existing surgical needles, however not all needles are suitable for this design.
..be sterile	OK	The modular design of the NID makes sterilization simple.
..be safe in use.	/	Since the design is not manufactured, this requirement has not been verified.

8 Discussion

The goal of this thesis was to present a conceptual design of a needle insertion device (NID) that is able to respond to- and compensate for breathing-induced lesion motion located inside the liver. This thesis introduces a novel method for needle insertion into moving targets. The method combines two motion management techniques which currently are mostly practised in radiotherapy.

An evaluation of the proposed design shows that most of the requirements are met. Some requirements, however, could not be verified as they are dependent to the precision of manufacturing process (e.g. maximum error in hitting the target and safety). With available 3D printers, the components can be manufactured with an acceptable precision (error of less than 1 mm). The error of the NID also depends on the accuracy of the actuators (motors).

The exemplary tumour path presented to the NID shows that, with the known x- and y-positions, the positioning of the NID can be realized. By transforming the tumour position (x, y) to the cylindrical coordinate system of the NID (r, θ) and presenting this data to the formulation presented in this study, the NID can formulate the actuators parameters (motor rotation) to hit the moving target.

There were some limitations to the current design which need to be considered before trial experiments and subsequently clinical implementation can be realized.

In the current design, the NID is only capable of 2D motion. Since the tumours motions crosses multiple planes, 3D motion would be preferred. This can be realised by adding another internal gear that is perpendicular to the excising one. However, the 2D motion of the device was based on the 2D motion of tumour (superior-inferior and anterior-posterior motions). Even the current design should be capable of covering the motion of the target, if it is positioned in the plane of the tumour motion.

The dimensional specifications of the device were designed in a way that they meet the (quite) realistic assumptions made in this study (e.g. insertion depth, insertion time period, etc.). The dimensions can further optimized to decrease the total weight of the device while providing enough stability and strength. Currently, the design is not very compact. The needle length, maximum insertion depth and release mechanism require the radius of the NID to be quite large. The device should not interfere with the workspace of the medical professional.

To validate the design some kind of simulation or real-life experiments are necessary. Since the conceptual design described in this thesis has not been manufactured, no real experiments were done.

In section 3.4 a number of assumptions were made. In this thesis the design was based on a prescribed tumour motion. In practice, the real tumour motion can be extracted using ultrasound data, or 4D CT scans. Alternatively, the motion of the target can be estimated using some external markers (chest skin markers) as surrogate signals and implementing deep learning techniques.

It was assumed that, because of the high insertion speed, the needle insertion causes no tissue deformation. Even though the amount of deformation decreases when the insertion velocity increases, in practice it's still present. This needs to be studied and integrated in the control of the NID. The same can be said for needle deflection.

Once the design is finalized, manufactured, tested and shows the capability of providing steady, quick and accurate needle delivery it can indicate that the proposed robotic needle insertion technique has the potential of bringing in high targeting accuracy, reliability and patient safety and reducing the needle placement duration in while breathing normally.

9 Conclusion

The goal of this report was to present a conceptual design of a needle insertion device (NID) that is able to respond to- and compensate for respiratory-induced lesion motion located inside the liver.

The proposed technique to achieve respiratory-induced motion compensation is to combine two motion management techniques; gating and chasing.

This thesis and its conceptual design could provide a foundation for studying the proposed robotic needle insertion technique.

A Appendix 1 - MATLAB

Proof of Concept Code.

```
function [x,y]=tracage_ellipse(xc,yc,a,b)
m = 1000;            % tumour locations
xc = 80;             % center x coordinate
yc = 20;             % center y coordinate
a = 2;               % oval width
b = 15;              % oval hight
rp= 50 ;             % radius pinion
rn= 200 ;            % radius NID
x = zeros(m,1);
y = zeros(m,1);

theta = linspace(0,2*pi,m);

for k = 1:m
x(k) = a * cos(theta(k));
y(k) = -b * sin(theta(k));
end

alpha = -(pi/10);

R  = [cos(alpha) -sin(alpha); ...
sin(alpha)  cos(alpha)];

rCoords = R*[x' ; y'];   % [] to create a 2xm array

xr = rCoords(1,:)';      % extract the rotated x coordinates
yr = rCoords(2,:)';      % extract the rotated y coordinates

xt= xr+xc ;          % x coordinate tumour
yt= yr+yc ;          % y coordinate tumour

Thetap= -(((atan(xt./yt).*rn)./rp));

ThetaDeg=rad2deg(Thetap);

figure(1)
plot(xt,yt,'LineStyle','--');
title('Tumour motion path');
xlabel('x-position'); ylabel('y-postion')

axis equal

figure(2)
plot(ThetaDeg);
title('Pinion Rotation');
xlabel('tumour location point'); ylabel('rotation (deg)')
```

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